DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

ev3 Inc.
% Mr. David Worrell, MS, RAC
Manager, Regulatory Affairs
9600 54th Avenue North
Plymouth, Minnesota 55442

Re: K021563
Trade/Device Name: IntraCoil® Peripheral Stent
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: May 10, 2002
Received: May 13, 2002

Dear Mr. Worrell:

This letter corrects our substantially equivalent letter of May 31, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3120 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K021563

Device Name: IntraCoil® Peripheral Stent

Indication For Use:

The IntraCoil® Peripheral Stent is indicated for use in the treatment of bronchial strictures produced by malignant neoplasms.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTIUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K021563

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Premarket Notification (510(k)) Summary

510(k) Number: K021563

Product Name: IntraCoil® Self-expanding Peripheral Stent

Common Name: Tracheal prosthesis

Class: II per 21 CFR 878.3720 (tracheal prosthesis)

Submitter's Name:
ev3 Inc.
9600 54th Avenue North
Plymouth, MN 55442

Official Contact:
David Worrell
Regulatory Affairs Manager
Telephone: 763-398-7000
Fax: 763-398-7200

Summary Preparation Date: May 1, 2006

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission. Substantial equivalence is claimed to the IntraCoil® Self-expanding Peripheral Stent, K990221/K001257.

The IntraCoil Stent is a self-expanding nickel-titanium (Nitinol) coil premounted on a delivery catheter. The stent is provided in diameters 4 to 8 mm, and lengths of 40 and 60 mm. The stent is indicated for use in the treatment of bronchial strictures produced by malignant neoplasms. Upon deployment the stent expands to conform to the bronchial lumen surface.

This 510(k) covers addition of the 8 x 60 mm stent. Otherwise, the device is identical to the IntraCoil Stent as previously cited. A subset of the *in vitro* performance tests conducted for K990221/K001257, and relevant to the modification, were repeated for design verification and product validation.